

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s)	Alchas et al.	Examiner:	Unassigned
Serial No.:	Unassigned	Group Art Unit:	Unassigned
Confirmation No:	Unassigned	Docket:	102-525 CIP/DIV (P-5258)
Filed:	Herewith	Dated:	November 25, 2003
For:	PREFILLABLE INTRADERMAL DELIVERY DEVICE		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

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Alexandria, Virginia 22313-1450  
*On: November 25, 2003*

Signed: Amanda F. Shaw

Amanda F. Shaw

**INFORMATION DISCLOSURE STATEMENT**

Sir:

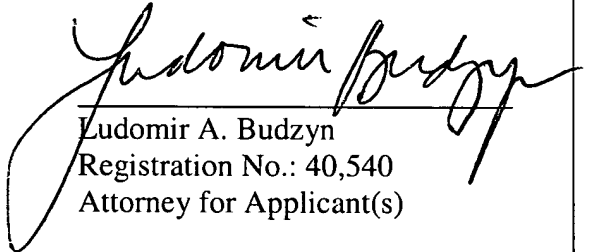
In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicants submit herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

This application is a division of U.S. Patent Application No. 09/835,248, filed April 13, 2001 which is a continuation-in-part of U.S. Patent Application No. 09/417,671. Pursuant to 37 C.F.R. §1.98(d) and the PTO's waiver of the requirement under 37 C.F.R. §1.98(a)(2)(i) (1276 OG 55), no copies of these references are being submitted herewith.

As this Information Disclosure Statement is being filed with the application, the Statement is believed to be timely in accordance with 37 C.F.R. §1.97 (b)(1), and accordingly no fee is due. If, however, a fee is due, please charge our Deposit Account No. 08-2461.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,



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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	ATTY. DOCKET NO. 102-525 CIP/DIV (P-5258)	SERIAL NO. Unassigned
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	FILING DATE Herewith	GROUP Unassigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		1,934,046	11/07/33	Demarchi			
		2,876,770	03/10/59	White			
		3,400,715	09/10/68	Pederson			
		4,060,073	11/29/77	Collica et al.			
		4,270,537	06/02/81	Romaine			
		4,373,526	03/15/93	King			
		4,583,978	04/22/86	Porat et al.			
		4,596,556	06/24/86	Morrow et al.			
		4,769,003	09/06/88	Stamler			
		4,790,824	12/13/88	Morrow et al.			
		4,883,573	11/28/89	Thomas			
		4,886,499	12/12/89	Cirelli et al.			
		4,898,588	02/06/90	Roberts			
		4,940,460	07/10/90	Casey, I. et al.			
		4,941,880	07/17/90	Burns			
		4,955,871	09/11/90	Thomas			

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		4,978,344	12/18/90	Dombrowski et al.			
		5,015,235	05/14/91	Crossman			
		5,064,413	11/12/91	McKinnon et al.			
		5,071,353	12/10/91	Van der Wal			
		5,141,496	08/25/92	Dalto et al.			
		5,190,521	03/02/93	Hubbard et al.			
		5,222,949	06/29/93	Kaldany			
		5,295,975	03-1994	Lockwood, Jr.			
		5,312,335	05/17/94	McKinnon et al.			
		5,331,954	07/26/94	Rex et al.			
		5,334,144	08/02/94	Alchas et al.			
		5,339,163	08/16/94	Homma et al.			
		5,368,578	11/29/94	Covington et al.			
		5,383,851	01/24/95	McKinnon, Jr. et al.			
		5,417,662	05/23/95	Hjerman et al.			
		5,431,155	07/11/95	Marelli			
		5,437,647	08/01/95	Firth et al.			
		5,466,220	11/14/95	Brenneman			

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		5,480,381	01/02/96	Weston			
		5,496,286	03/05/96	Stiehl et al.			
		5,503,627	04/02/96	McKinnon et al.			
		5,514,107	05/07/96	Haber et al.			
		5,520,639	05/28/96	Peterson et al.			
		5,527,288	06/18/96	Gross et al.			
		5,569,189	10/29/96	Parsons			
		5,578,014	11/26/96	Erez et al.			
		5,582,598	12/10/96	Chanoch			
		5,599,302	02/04/97	Lilley et al.			
		5,649,912	07/22/97	Peterson			
		5,665,071	09/09/97	Wyrick			
		5,702,362	12/30/97	Herold et al.			
		5,704,911	01/06/98	Parsons			
		5,779,677	07/14/98	Frezza			
		5,873,856	02/23/99	Hjertman et al.			
		5,879,327	03/09/99	Moreau De Farges et al.			
		5,891,085	04/06/99	Lilley et al.			

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		5,893,397	04/13/99	Peterson et al.			
		5,921,963	07/13/99	Erez et al.			
		5,957,897	09/28/99	Jeffrey			
		5,961,495	10/05/99	Walters et al.			
		5,993,412	11/30/99	Deily et al.			
		6,001,089	12/14/99	Burroughs et al.			
		6,004,299	12/21/99	Arai et al.			
		6,036,675	03/14/00	Thorne et al.			
		6,053,893	04/25/00	Bucher			
		6,083,197	07/04/00	Umbaugh			
		6,090,077	07/18/00	Shaw			
		6,090,080	07/18/00	Jost et al.			
		6,090,082	07/18/00	King et al.			
		6,093,170	07/25/00	Hsu et al.			
		6,099,504	08-2000	Gross et al.			
		6,112,743	09/05/00	Denton			
		6,200,291	03/13/01	DiPietro			
		6,436,068	08-2002	Bardy			

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
		2000-37456	02/08/00	Japan				
		DE 41 27 887 C1		Germany				
		EP 0 279 583 B1	10/06/93	EPO				
		EP 0 904 790 A2		EPO				
		FR 612 401 A1		France				
		GB 2 206 794 A		United Kingdom				
		WO 95/01198		PCT				
		WO 97/13537	04/17/97	PCT				
		WO 97/37705	10/16/97	PCT				
		WO 99/27986		PCT				
		WO 99/34850		PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Article: CLINICAL DO's & DON'TS - GIVING INTRADERMAL INJECTIONS by Edwina Mcconnell, RN, PhD
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			Article: DERMAL IMMUNE SYSTEM by Brian J. Nickoloff, MD, PhD
			Article: INJECTION TECHNIQUE INTRADERMAL
			Article: INTRADERMAL GENE IMMUNIZATION: THE POSSIBLE ROLE OF DNA UPTAKE IN THE INDUCTION OF CELLULAR IMMUNITY TO VIRUSES by Eyal Raz et al.
			Article: MONOGRAPHS OF THE PHYSIOLOGICAL SOCIETY NO. 12: SUBSTANCES PRODUCING PAIN AND ITCH by C.A. Keele and D. Armstrong Pub: The Williams & Wilkins Company (1964)
			Article: THE DENDRITIC CELL SYSTEM AND ITS ROLE IN IMMUNOGENICITY by Ralph Steinman
			Article: TRIALS OF INTRADERMAL HEPATITIS B VACCINES IN GAMBIAN CHILDREN by Whittle, Lam, Ryder
			<i>Purified Influenza Vaccine: Clinical and Serologic Responses to Varying Doses and Different Routes of Immunization</i> , by C.A. Philips, B.R. Forsyth, W.A. Christmas, D.W. Gump, E.B. Whorton, I. Rogers, and A. Rudin, from the Department of Medicine and Community Medicine, University of Vermont College of Medicine, Burlington, Vermont.
			<i>Polyvalent Influenza Vaccine: Comparison of Jet Injection with Intradermal and Subcutaneous Syringe Methods of Administration</i> , authored by Mervin L. Clark, Herbert Reinhardt, M. Clinton Miller, III and Ray Wilson, Oklahoma City, Oklahoma.
			<i>Experimental Comparison of Intradermal and Subcutaneous Vaccination with Influenza Vaccine</i> , from the American Journal of Medical Technology, Vol. 31, November-December 1965, No. 6.

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			<i>Intradermal Influenza Immunization, Experience with Hong Kong Vaccine, from the American Review of Respiratory Disease, Vol. 103, 1971.</i>
			<i>Efficacy of Adsorbed Trivalent Split Influenza Vaccine Administered by Intradermal Route, by I. Th. Niculescu, Eugenia Zilisteanu, V. Alexandrescu, Mihaela Matepiuc, Ligia Cretescu, N. Ionescu, G. Molnar, R. Racasan and Adina Mogos, received for publication December 4, 1980, from Arch. Roum. Path. Exq. Microbiol., T. 40, No. 1, pp. 67-70, Janvier-Mars, 1981.</i>
			<i>Efficacy of Intradermally Administered A2 Hong Kong Vaccine, from Jama, from JAMA, July 6, 1970, Vol. 213, No. 1</i>
			<i>Comparison of Responses to Influenza, A-New Jersey/76-A/Victoria/75 Virus Vaccine Administered Intradermally or Subcutaneously to Adults with Chronic Respiratory Disease, authored by F. Alexander Herbert, R.P. Bryce Larke, and Edythe L. Markstad, from the Journal of Infectious Diseases, Vol. 140, No. 2, August 1979.</i>
			<i>A Comparison of the Intradermal and Subcutaneous Routes of Influenza Vaccination with A/New Jersey/76 (Swine Flu) and A/Victoria/75: Report of a Study and Review of the Literature, by William Halperin, MD, MPH, William I. Weiss, MD, Ronald Altman, MD, MPH, Michael A. Diamond, MD, Kenneth J. Black, BA, Alfred W. Iaci, BBA, MS, Henry C. Black, DVM and Martin Goldfield, MD, from the ALPHA December 1979, Vol. 69, No. 12.</i>
			<i>Effect of Dosage and Route of Inoculation Upon Antigenicity of Inactivated Influenza Virus Vaccine (Hong Kong Strain) in Man, from Bull. Org. mond. Santé Bull. Wld Hlth Org. 1969, 41, 507-516.</i>
			<i>Comparative Analysis of Six European Influenza Vaccines, from Eur. J. Clin. Microbiol. Infect. Dis. 1996, 15:121-127.</i>
			<i>Morphological and Biochemical Characterization of Influenza Vaccines Commercially Available in the United Kingdom, by F. Renfrey and A. Watts, from Vaccine 1994, Vol. 12, No. 8.</i>
			<i>Influenza Immunization Policies and Practices in Japan, from the Journal of Infectious Diseases, Vol. 141, No. 2, February 1980.</i>

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			<i>Clinical Immunogenicity and Tolerance Studies of Liquid Vaccines Delivered by Jet-Injector and a New Single-Use Cartridge (Imule®): Comparison with Standard Syringe Injection</i> , authored by Isabelle Parent du Chatelet, Jean Lang, Martin Schlumberger, Emmanuel Vidor, Georges Soula, Alain Gene, Steven M. Standaert, Pierre Saliou and Imule® Investigators Group, Vaccine 1997, Vol. 15, No. 4.
			Abstract: <i>Does a Needleless Injection System Reduce Anxiety in Children Receiving Intramuscular Injections?</i> , by Polillio AM, Kiley J, from the Pediatric Primary Care Clinic, Boston City Hospital, MA, USA. <i>Pediatr. Nurs.</i> 1997, January-February; 23(1): 46-9.
			Abstract: <i>Intradermal Administration of Viral Vaccines</i> , by Nagafuchi S., Kashiwagi S, Imayama S, Hayashi J, Niho Y, from <i>Rev. Med. Virol.</i> 1998 April; 8(2):97-111.
			Abstract: <i>Letter: Intradermal Influenza Vaccination</i> , by Payler DK, Skirrow MB, <i>Br Med J</i> 1974 June 29; 2(921);727.
			Intradermal Influenza Vaccination; <i>British Medical Journal</i> , June 29, 1974.
			Smith Kline Beecham Meeting Agenda

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